UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

09 CV 8544

SKANDIA LIFE INSURANCE COMPANY LTD.,

Plaintiff,

v.

JEFFREY B. KINDLER, DENNIS A. AUSIELLO, MICHAEL S. BROWN, M. ANTHONY BURNS, ROBERT N. BURT, W. DON CORNWELL, WILLIAM H. GRAY, III, CONSTANCE J. HORNER, WILLIAM R. HOWELL, STANLEY O. IKENBERRY, SUZANNE NORA JOHNSON, JAMES M. KILTS, GEORGE A. LORCH, HENRY A. MCKINNELL, DANA G. MEAD, FRANKLIN D. RAINES, DAVID L. SHEDLARZ, RUTH J. SIMMONS, WILLIAM C. STEERE, JR.,JEAN-PAUL VALLES, FRANK D'AMELIO, JOSEPH M. FECZKO, DOUGLAS M. LANKLER, and IAN C. READ

Defendants,

and

PFIZER, INC.,

Nominal Defendant.

Civil Action. No:

VERIFIED DERIVATIVE COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Skandia Life Insurance Company Ltd., ("Plaintiff"), by and through Plaintiff's undersigned attorneys, hereby submits this Verified Shareholder Derivative Complaint (the "Complaint") for the benefit of nominal defendant Pfizer, Inc. ("Pfizer" or the "Company"), against certain current and former members of Pfizer's Board of Directors (the "Board") and Pfizer executive officers, seeking to remedy defendants' breaches of fiduciary duties and unjust enrichment from 2001 to the present (the "Relevant Period").

NATURE OF THE ACTION AND OVERVIEW

1. This is a shareholder derivative action to recover damages on behalf of Pfizer and its shareholders resulting from pervasive, long-standing and illegal schemes employed by Pfizer employees to: (a) market and promote four Pfizer pharmaceutical products (Bextra, Geodon, Zyvox and Lyrica) for "off label" uses not approved by the United States Food and Drug Administration (the "FDA"), in violation of the Food, Drug , and Cosmetics Act (the "FDCA"), 21 U.S.C. § 301 *et seq*., and the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*., and (b) market and promote these four drugs, together with at least nine others (namely, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec), through a variety of improper and illegal "kickbacks" provided to health care providers and professional in order to induce further prescriptions of and revenues from those drugs.

2. Ultimately, this regulatory misconduct subjected Pfizer, as revealed in September 2009, to a record $2.3 billion in criminal fines and civil penalties levied upon Pfizer by federal regulators, to further legal costs and exposures (e.g., product liability and consumer fraud litigation) for which Pfizer has already reserved or expended nearly $1 billion more, and to substantial impairment of Pfizer's reputation in the market, the healthcare industry, and regulatory arenas.

3. The wide-ranging and long-standing misconduct with respect to the marketing, promotion and sale of these Pfizer products is all the more remarkable given, as detailed herein:

(a) that, contemporaneously, between 2002 and 2007, Pfizer reached three substantial settlements, whose combined fines exceeded $500 million dollars, with federal regulators over like drug marketing practices with respect to three drugs (Lipitor, Neurontin, and Genotropin) – and yet *continued* to employ those very practices, known to be misconduct and known to expose Pfizer to substantial costs and penalties, for at least thirteen more products;

(b) that, as one result of this history of regulatory misconduct, Pfizer was required to enter into two "Corporate Integrity Agreements" in 2002 and 2004 and to adopt a Code of

Conduct and Business Ethics in 2004, which, as the Department of Justice explained in 2004, were designed to ensure that "*any future off-label marketing conduct is detected and corrected on a timely basis*" (emphasis added). This was accomplished by mandating that Pfizer establish and maintain numerous positions (*e.g.*, a Compliance Officer at the senior management level), policies (*e.g.*, a Code of Conduct that Pfizer's officers and directors were required to adopt and abide by, placing compliance oversight squarely and explicitly in the directors and officers' purview), and procedures (*e.g.*, requiring the Compliance Officer to report to and meet with the Board at least semi-annually on compliance matters, further authorizing the Compliance Officer to report compliance matters to the Board on an *ad hoc* and as-needed basis, and establishing a "disclosure program" to encourage employee reporting and disclosure of regulatory noncompliance and/or misconduct, purportedly protected by nonretaliation and anonymity policies). The institution within Pfizer of these structures was meant to, and worked to, ensure that Pfizer's Board was provided with sufficient and accurate information to monitor regulatory compliance and act when needed to bring Pfizer's operations into compliance; and

(c) that, in addition to the heightened awareness of the importance of and responsibility for compliance brought on by the fines and regulatory settlements described in (a) *supra*, and in addition to the improved information flow channeled to the Board as a result of Corporate Integrity Agreements described in (b) *supra*, numerous further "red flags" evidencing regulatory misconduct and illegal marketing and promotion of Pfizer drugs for off-label uses and via operation of kickback schemes were further presented to Pfizer's officers and directors, both: (i) by numerous Pfizer employees, through the "disclosure program" and ultimately through more than ten whistle-blower actions detailing such misconduct and practices; and (ii) by the FDA itself, which during the Relevant Period repeatedly sent letters, warnings and notifications to senior Pfizer officers and marketing/operations executives (including Pfizer's Chairman and CEO) complaining of Pfizer's misleading and/or false drug marketing and promotions, including improper off-label marketing and promotion of Bextra, Geodon and Zyvox.

4. The resulting record-breaking $2.3 billion of criminal fines and civil payments imposed upon Pfizer in September 2009 were calibrated, as regulators made explicit, not merely to size and scope of the misconduct, but to its enduring wilfulness. Not only did Pfizer violate the law repeatedly and consistently, with respect to a wide array of products and over a very long period of time, but, as the government's prosecuting attorney noted, "*at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws*. Today's enormous fine demonstrates that such *blatant and continued disregard of the law* will not be tolerated". (emphasis added).

5. Defendants here – Pfizer officers and directors during the Relevant Period – utterly failed to discharge the fiduciary duties imposed upon them by virtue of their positions, as well as the heightened awareness of such duties with specific respect to compliance matters imposed by virtue of Pfizer's contemporary regulatory run-ins, by virtue of the Code of Conduct that explicitly placed compliance oversight in their purview, and by virtue of the operation of the compliance information reporting mechanisms that was designed to and did funnel information concerning compliance misconduct and failures to them. Given these specific and extraordinary circumstances, it is plain that Defendants either consciously disregarded consistent, repeated evidence of widespread and consequential misconduct, or affirmatively condoned such misconduct.

JURISDICTION

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1332 (a)(2). Plaintiff and defendants are citizens of different states, and the amount in controversy exceeds $75,000.

7. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District so as to render the exercise of jurisdiction by this District permissible under traditional notions of fair play and substantive

justice.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(a). Pfizer maintains its principal place of business in the District, and a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, occurred in this District.

PARTIES

9. Plaintiff Skandia Life Insurance Company Ltd. is a current shareholder of Pfizer and has continuously held Pfizer stock during the Relevant Period.

10. Nominal defendant Pfizer, Inc. ("Pfizer"), a Delaware corporation headquartered in New York, New York, engages in the discovery, development, manufacture and marketing of prescription medicines for humans and animals worldwide. Pfizer is the world's largest pharmaceutical company.

11. Defendant Jeffrey B. Kindler ("Kindler") served as Pfizer's Chief Executive Officer and as Board director since July 2006, and as Chairman of the Board since December 2006. Defendant Johnson signed the registration statement for the Secondary Offering. During the Relevant Period, Kindler also served: (1) as Pfizer's Vice Chairman and General Counsel from March 2005 to July 2006; (2) as Pfizer's Chief Compliance Officer from approximately August 2005 to March 2007; (3) as Pfizer's Executive Vice President and General Counsel from April 2004 to March 2005; and (4) as Pfizer's Vice President and General Counsel from January 2002 to April 2004. McKinnell has received more than $35 million compensation for his service as a Pfizer officer and director since 2004. Upon information and belief, Kindler is a citizen of Connecticut.

12. Defendant Dennis A. Ausiello ("Ausiello") served as a director on Pfizer's Board since 2006. During the Relevant Period, Ausiello served as member of the Board's Audit Committee (since 2009) and as a member of the Board's Corporate Governance Committee (since 2007). Ausiello has received more than $570,000 compensation for his service as a Pfizer director. Upon information and belief, Ausiello is a citizen of Massachusetts.

13. Defendant Michael S. Brown ("Brown") served as a director on Pfizer's Board throughout the Relevant Period, since 1996. During the Relevant Period, Brown served as member of the Board's Corporate Governance Committee (since 2003). Brown has received more than $1.2 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Brown is a citizen of Texas.

14. Defendant M. Anthony Burns ("Burns") served as a director on Pfizer's Board throughout the Relevant Period, since 1988. During the Relevant Period, Burns served as member of the Board's Audit Committee (between 2005 and 2008), as a member of the Executive Committee (since 2001), and as a member of the Compensation Committee (between 2001 and 2004) and as Chair of the Compensation Committee (2003-2004). Burns has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Burns is a citizen of Florida.

15. Defendant Robert N. Burt ("Burt") served as a director on Pfizer's Board throughout the Relevant Period, since 2000. During the Relevant Period, Burt served as member of the Board's Audit Committee (between 2003 and 2005) and as a member of the Board's Compensation Committee (since 2005). Burt has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Burt is a citizen of Illinois.

16. Defendant W. Don Cornwell ("Cornwell") served as a director on Pfizer's Board throughout the Relevant Period, since 1997. During the Relevant Period, Cornwell served as chairman of the Board's Audit Committee (since 2007), as a member of the Board's Audit Committee (since 2003), and as a member of the Board's Compensation Committee (since 2009). Cornwell has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Cornwell is a citizen of New York.

17. Defendant William H. Gray III ("Gray") served as a director on Pfizer's Board throughout the Relevant Period, since 2000. During the Relevant Period, Gray served as member of the Board's Corporate Governance Committee (since 2001). Gray has received more than

$975,000 compensation for his service as a Pfizer director since 2002. Upon information and belief, Gray is a citizen of Florida.

18. Defendant Constance J. Horner ("Horner") served as a director on Pfizer's Board throughout the Relevant Period, since 1993. During the Relevant Period, Horner served as member of the Board's Corporate Governance Committee (since 2004), as chairwoman of the Corporate Governance Committee (between 2006 and 2008), and as a member of the Executive Committee. Horner has received more than $1 million compensation for her service as a Pfizer director since 2002. Upon information and belief, Horner is a citizen of Virginia.

19. Defendant William R. Howell ("Howell") served as a director on Pfizer's Board between June 2000 and April 2009. During the Relevant Period, Howell served as member of the Board's Audit Committee (between 2005 and 2008), and as chairman of the Audit Committee (between April 2005 and 2006), and as a member of the Executive Committee. Howell has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Howell is a citizen of Wyoming.

20. Defendant Stanley O. Ikenberry ("Ikenberry") served as a director on Pfizer's Board between 1982 and March 2007. During the Relevant Period, Ikenberry served as Pfizer's Lead Independent Director (between October 2005 and February 2007), as member of the Board's Compensation Committee (between 2005 and 2006), and as a member of the Board's Corporate Governance Committee (between 2003 and 2004). Ikenberry has received more than $650,000 compensation for his service as a Pfizer director since 2002. Upon information and belief, Ikenberry is a citizen of Illinois.

21. Defendant Suzanne Nora Johnson ("Johnson") served as a director on Pfizer's Board since September 2007. During the Relevant Period, Johnson served as member of the Board's Audit Committee (since 2007) and as a member of the Board's Compensation Committee (since 2009). Johnson has received more than $375,000 compensation for her service as a Pfizer director since 2007. Upon information and belief, Johnson is a citizen of California.

22. Defendant James M. Kilts ("Kilts") served as a director on Pfizer's Board since September 2007. During the Relevant Period, Kilts served as member of the Board's Compensation Committee (since 2007). Kilts has received more than $365,000 compensation for his service as a Pfizer director since 2007. Upon information and belief, Kilts is a citizen of New York.

23. Defendant George A. Lorch ("Lorch") served as a director on Pfizer's Board throughout the Relevant Period, since 2000. During the Relevant Period, Lorch served as member of the Board's Compensation Committee (since 2001). Lorch has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Lorch is a citizen of Florida.

24. Defendant Henry A. McKinnell ("McKinnell") served as a director on Pfizer's Board throughout between June 1997 and February 2007. During the Relevant Period, McKinnell served as the Chairman of Pfizer's Board (between 2001 and December 2006), as Pfizer's Chief Executive Officer (between 2001 and July 2006). McKinnell has received more than $26 million compensation for his service as a Pfizer officer and director since 2002. Upon information and belief, McKinnell is a citizen of Wyoming.

25. Defendant Dana G. Mead ("Mead") served as a director on Pfizer's Board throughout the Relevant Period, since 1998. During the Relevant Period, Mead served as member of the Board's Compensation Committee (since 2003), and as chairman of the Board's Compensation Committee (since 2005). Mead has received more than $1 million compensation for his service as a Pfizer director since 2002. Upon information and belief, Mead is a citizen of Massachusetts.

26. Defendant Franklin D. Raines ("Raines") served as a director on Pfizer's Board between October 1998 and April 2005. During the Relevant Period, Raines served as member of the Board's Compensation Committee (between 2003 and 2004). Raines has received more than $210,000 compensation for his service as a Pfizer director since 2002. Upon information

and belief, Raines is a citizen of the District of Columbia.

27. Defendant David L. Shedlarz ("Shedlarz") served as a director on Pfizer's Board between March 2005 and December 2007. During the Relevant Period, McKinnell served as Pfizer's Vice Chairman (between March 2005 and December 2007), as Pfizer's Chief Financial Officer (between1995 and March 2005), and as a Pfizer Executive Vice President (between 1999 and March 2005). Shedlarz has received more than $10 million compensation for his service as a Pfizer officer and director since 2003. Upon information and belief, Shedlarz is a citizen of New York.

28. Defendant Ruth J. Simmons ("Simmons") served as a director on Pfizer's Board between January 1997 and April 2007. During the Relevant Period, Simmons served as member of the Board's Corporate Governance Committee (between 2003 and 2006), and as chairwoman of the Corporate Governance Committee (between 2004 and 2005). Simmons has received more than $600,000 compensation for her service as a Pfizer director since 2002. Upon information and belief, Simmons is a citizen of Texas.

29. Defendant William C. Steere, Jr. ("Steere") served as a director on Pfizer's Board throughout the Relevant Period, since 1987. During the Relevant Period, Steere served as Pfizer's Chairman Emeritus (since July 2001); prior to the Relevant Period, Steere served as Pfizer's Chief Executive Officer (between 1991 and 2000) and as Pfizer's Chairman of the Board (between 1992 and April 2001). Steere has received more than $840,000 compensation for his service as a Pfizer director since 2002. Upon information and belief, Steere is a citizen of Florida.

30. Defendant Jean-Paul Vallés ("Vallés ") served as a director on Pfizer's Board between 1980 and June 2005. During the Relevant Period, Vallés served as member of the Board's Audit Committee (between 2003 and 2004). Vallés has received more than $200,000 compensation for his service as a Pfizer director since 2002. Upon information and belief, Vallés is a citizen of New York.

31. Defendants Kindler, Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Howell, Ikenberry, Johnson, Kilts, Lorch, McKinnell, Mead, Raines, Shedlarz, Simmons, Steere,

and Vallés are hereinafter collectively referred to as the "Director Defendants".

32. Defendant Frank A. D'Amelio ("D'Amelio") served as Pfizer's Chief Financial Officer ("CFO") since September 2007. D'Amelio received more than $8.1 million in compensation for his service to Pfizer in 2008. Upon information and belief, D'Amelio is a citizen of New Jersey.

33. Defendant Joseph M. Feczko ("Feczko") served as Pfizer's Chief Medical Officer from 2006 to 2009. Upon information and belief, Feczko is a citizen of Connecticut.

34. Defendant Douglas M. Lankler ("Lankler") served as Pfizer's Senior Vice President, Associate General Counsel and Chief Compliance Officer since April 2008. Upon information and belief, Lankler is a citizen of New York.

35. Defendant Ian Read ("Read") served as Pfizer's Senior Vice President and President, Worldwide Pharmaceutical Operations, during the Relevant Period. Read received more than $6.8 million compensation for his service to Pfizer in 2008. Upon information and belief, Read is a citizen of Connecticut.

36. Defendants Kindler, D'Amelio, Feczko, Kindler, Lankler, McKinnell, Read and Shedlarz are collectively referred to as the "Officer Defendants".

37. The defendants identified in ¶¶ 10-30 and 32-35 above are hereinafter referred to as "Defendants".

38. Those Defendants who served on Pfizer's Board's Audit Committee – namely, Defendants Ausiello, Burns, Burt, Cornwell, Howell, Johnson, and Vallés – are hereinafter referred to as the "Audit Committee Defendants".

39. Those Defendants who served on Pfizer's Board's Corporate Governance Committee – namely, Defendants Ausiello, Brown, Gray, Horner, Ikenberry and Simmons – are hereinafter referred to as the "Corporate Governance Committee Defendants".

40. Non-party Stephen W. Sanger ("Sanger") served as a director on Pfizer's Board beginning February 2009.

BACKGROUND

A. Pfizer and Its Products

41. Pfizer, including various wholly-owned subsidiaries such as Pharmacia (whose acquisition by Pfizer was announced in July 2002 and completed in April 2003) and Warner Lambert (whose acquisition by Pfizer was completed in June 2000), is one of the world's largest pharmaceutical companies.

42. During 2008, nine separate Pfizer pharmaceuticals – Lipitor, Norvasc, Lyrica, Celebrex, Viagra, Detrol/Detrol LA, Xalatan/Xalacom, Geodon and Zyvox– each generated $1 billion or more in yearly sales, and alone accounted for approximately 28% of Pfizer's total pharmaceutical revenues (Pfizer, *Form 10-K*, February 27, 2009, at p. 16). Concerning these "blockbuster" drugs and their outsize importance to Pfizer's business and financial performance, Pfizer noted in its SEC filings that a "significant" impact on Pfizer's financial performance could ensue should those drugs "become subject to problems such as. . . regulatory proceedings" (*Ibid*.).

43. As detailed herein, Pfizer's illegal marketing, promotion and sale practices – which sought to increase drug sales of at least 13 different Pfizer products over the course of nearly eight years via promotion and marketing of, and sales for, off-label uses and dosages, and via kickbacks to healthcare providers to induce further prescriptions – involved seven of Pfizer's above-mentioned nine most important, best-selling drugs, namely: Lipitor, Norvasc, Lyrica, Celebrex, Viagra, Geodon, and Zyvox.

44. The length of time (nearly eight years), the array of products (at least thirteen different drugs), and the centrality of those products to Pfizer's performance (seven of Pfizer's nine best-selling, $1 billion-or-more-per-year pharmaceuticals), all indicate that the misconduct and regulatory violations were in no way "isolated" incidents engaged in by a handful of wrongdoers, but rather constituted consistent, enduring Company-wide practice and/or policy for many of Pfizer's most material and important pharmaceuticals.

B. Relevant Regulations Applying to Pfizer's Business and Operations

1. The FDA, the FDCA, and "Off-Label" Drug Marketing

45. Pfizer's business is subject to extensive regulation by the Food and Drug Administration (the "FDA"), which regulates the development, manufacture and distribution of drugs in the United States. Under the Food, Drug , and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq*., new pharmaceuticals cannot be marketed in the U.S. unless the drug's sponsor demonstrates to FDA satisfaction – generally requiring a multi-year process of clinical study and testing – that the drug is (1) effective, for (2) an intended use at (3) a given dosage, while (4) being safe. To emphasize: the FDA does not approve a drug for treatment of sicknesses in general, but rather approves (1) specific dosages of a drug to (2) treat a specific condition, after (3) rigorous testing of those dosages applied to patients with those conditions demonstrates efficacy and safety. The FDA-approved used is termed the "indication" – the 'condition' for which the drug may be prescribed; and the contained within the FDA approval of the drug is an approval of the specific dosage or dosages which testing revealed to be effective and safe.

46. FDA-approved indications and dosages are set forth in a drug's "labeling", whose contents must also be reviewed and approved by the FDA. The FDA will only approve a new drug application if the drug's labeling conforms to the indications and dosages approved by the FDA on the basis of the clinical evidence submitted to it. *See* 21 U.S.C. §§ 352, 355(d).

47. Any use of a drug that is inconsistent with or outside the scope of the drug's FDA-approved label – either in terms of indications or conditions for which it is prescribed as a treatment, or in terms of the dosages prescribed – is termed "off-label" use.

48. Although doctors may prescribe drugs off-label if medically appropriate, the FDCA makes it illegal for drug manufacturers to promote or market a drug for any off-label uses. *See* 21 U.S.C. §§ 333, 352. Specifically, a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose, and a manufacturer illegally "misbrands" a drug if the drug's labeling – which includes all marketing and promotional materials relating to the drug – describes intended uses for the drug that have not been approved by the FDA.

Id.

49. Should a manufacturer wish to market or promote an FDA-approved drug for alternative uses – i.e., uses not listed on the approved label – the manufacturer must resubmit the drug for another series of clinical trials designed to produce relevant evidence, one way or another, as to the drug's efficacy and safety for such alternative indications and/or dosages. *See* 21 U.S.C. § 360aaa.

50. In sum, the on-label, off-label regulatory scheme protects patients and consumers by ensuring that drug companies do not promote drugs for uses other than those found – after rigorous clinical testing reviewed by an independent governmental body (the FDA) – to be effective and safe.

51. Pharmaceutical companies that violate FDCA prohibitions against misbranding and promotion of off-label, un-FDA-approved uses subject themselves to potentially severe penalties, including criminal prosecution, injunctions, and seizures of misbranded or unapproved drugs. Pharmaceutical companies convicted of a crime under the FDCA may be subject to "debarment", or exclusion, from Federal healthcare programs such as Medicare and Medicaid. As Medicaid and like governmental programs are the largest purchasers of prescription drugs, this would be a catastrophic outcome for almost any pharmaceutical company.

2. Federal Health Care Program Regulations Provide Funding/Reimbursement for Prescription Drugs Only for On-Label Usage or for Specific Off-Label Usages Explicitly Allowed by Such Programs

52. Federal reimbursement for prescription drugs under Medicaid, Medicare and like governmental programs is available only for "covered outpatient drugs", which in turn are those used for a "medically accepted indication". 42 U.S.C. §§ 1396b(I)(10), 1396r-8(k)(2), (3). A "medically accepted indication" is either: (1) the on-label use approved by the FDA, or (2) included in one of the drug compendia identified in the Medicaid statute. 42 U.S.C. § 1396r-k(k)(6).

53. Medicaid is the largest purchaser of prescription drugs in the U.S. If prescriptions for drugs provided under Medicaid and like programs are for off-label uses that are not

included in the above-mentioned compendia, Medicaid and like programs cannot fund/reimburse such uses.

54. Therefore, off-label marketing and promotion by drug manufacturers may, *inter alia*, constitute a fraudulent claim upon the government pursuant to the Federal False Claims Act. *See* 31 U.S.C. § 3729. The U.S. may recover for a violation of the Federal False Claims Act treble the damages the government sustained, in addition to civil monetary penalties. The Federal False Claims Act also contains Qui Tam ("whistle-blower") provisions that allow individual aware of fraud against the government to file suit on the government's behalf and receive a portion of any recovered funds.

3. The Federal Anti-Kickback Statute

55. The federal health care anti-kickback statute, 42 U.S.C. § 1320-7b(b), arose from Congressional concern that payoffs to healthcare providers can result in provision of unnecessary, inferior, or even dangerous healthcare products, services or treatments. To protect against such outcomes, Congress prohibits provision of kickbacks in any form, and specifically prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase of any item for which payment may be made under a federally-funded health care program. *Id*. The statute prohibits not only outright bribes and rebate schemes, but also any payment by pharmaceutical companies that has as one of its purposes the inducement of a physician to write additional prescriptions for that company's products. Violations of the statute subjects violators to imprisonment, civil monetary penalties, and exclusion from participation in federal health care programs. *Id*.

C. Pfizer's Contemporary History of Regulatory Violation, Illegal Off-Label Marketing, and Illegal Kickbacks, and the Resulting "Corporate Integrity Agreements" Entered Into By Pfizer

56. Between 2002 and 2007, as detailed below, Pfizer negotiated three separate settlements with governmental agencies including the Department of Justice ("DOJ") arising from: (1) fraudulent sales/charges relating to the drug Lipitor, resulting in fraudulent billings to and

improper reimbursement from Medicaid; (2) FDCA violations stemming from illegal off-label promotion of the drug Neurontin, and illegal kickbacks to healthcare providers to induce them to further prescribe Neurontin; and (3) FDCA violations stemming from illegal off-label promotion of the drug Genotropin.

57. These facts are relevant for two primary reasons.

58. First, and as explicitly noted by DOJ officials with respect to Pfizer's most recent $2.3 billion of settlements with the DOJ relating to illegal off-label promotions and kickbacks with respect to thirteen different Pfizer products between 2001 and 2008, Pfizer – at the very same time it was being punished for its activities with respect to Lipitor, Neurontin, and Genotropin – did not cease such activities but rather *continued* its illegal promotional practices on a far greater scale with respect to many more of its products. As acting U.S. Attorney for the District of Massachusetts, Mike Loucks explained with respect to the unprecedented size of Pfizer's recent penalties:

> The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes. . . Pfizer violated the law over an extensive time period. *Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws*. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated. (emphasis added)

59. Second, and as detailed herein, Pfizer's 2002 Lipitor settlement and 2004 Neurontin settlement both resulted in Pfizer's signing of "Corporate Integrity Agreements" whose primary purpose was to establish within Pfizer certain positions (*e.g.*, a Compliance Officer at the senior management or officer level), policies and procedures (*e.g.*, that the Compliance Officer make at least semi-annual reports to the Board and hold semi-annual meetings with the Board concerning compliance issues; that Pfizer retain an outside consultant to assess and evaluation compliance-related issues, procedures and controls; that Board members agree to abide by a Code of Conduct stating their responsibility for overseeing compliance; that Pfizer establish a procedure for employees to report compliance misconduct and adopt a policy of non-retaliation with respect to such reporting

employees) – all or which were designed to improve reporting of and oversight over compliance with applicable federal regulations.

60. Notwithstanding the heightened attention to regulatory compliance that the Corporate Integrity Agreements provided, and notwithstanding the numerous, heightened compliance reporting mechanisms and structures that the Corporate Integrity Agreements established in order to ensure that Pfizer's Board was provided with sufficient and accurate information to monitor regulatory compliance and act when needed to bring Pfizer's operations into compliance, Defendants, despite their awareness of the matters' general importance and despite the information they received as to Pfizer's noncompliance, consciously disregarded and/or affirmatively condoned continued, long-standing and widespread operational misconduct – such as off-label marketing and promotion, and kickbacks, occurring consistently over many years and with respect to many drugs, including seven of Pfizer's nine best-sellers – that violated applicable federal regulations and that ultimately resulted in substantial damage to the Company.

1. Pfizer's 2002 Lipitor Settlement and the 2002 Corporate Integrity Agreement

61. On October 28, 2002, Pfizer entered into a settlement with the DOJ to resolve a civil investigation into violations of the Federal False Claims Act stemming from illegal kickbacks paid to healthcare providers to induce them to further prescribe Pfizer's single best-selling drug, Lipitor (2008 Lipitor sales were $12.8 billion) and related fraudulent overcharges to Medicaid for Lipitor. The settlement related to conduct engaged in by Pfizer's wholly-owned subsidiary, Warner-Lambert, prior to Pfizer's 2000 acquisition of Warner-Lambert.

62. To settle these charges, Pfizer agreed to pay $49 million and to enter into a "Corporate Integrity Agreement" with the Department of Health and Human Services' Office of Inspector General

63. Pfizer's 2002 Corporate Integrity Agreement, which established within Pfizer internal positions, procedures and controls designed to prevent future compliance problems, provided *inter alia* that:

(a) the Corporate Integrity Agreement would be operative for a five-year period;

(b) Pfizer establish a Compliance Officer position at the senior management level;

(c) that the Compliance Officer "make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcomittee, in such form or manner as the Board of Directors determines), and shall be authorized to report on such matters to the Board of Directors at any time";

(d) Pfizer must retain, within 90 days of the agreement's commencement, an entity to assist it in assessing and evaluating its Medicaid compliance systems, processes, policies and practices; and

(e) Pfizer implement, within 120 days of the agreements's commencement, "written policies and procedures regarding the operation of Pfizer's Compliance Program, and its compliance with Federal health care requirements", and that such policies and procedures must address inter alia "promotional practices that conform with all applicable health care program requirements, including but not limited to, the Federal anti-kickback statute, codified at 42 U.S.C. § 1230a-7b".

64. Notwithstanding the 2002 Corporate Integrity Agreement and the numerous positions, procedures and policies it established within Pfizer to inform the Board of compliance misconduct and thus allow the Board to exercise compliance oversight, the Director Defendants and the Officer Defendants allowed Pfizer to continue to engage in long-standing, illegal promotional, marketing and sales misconduct throughout the Relevant Period with respect to numerous (at least thirteen) Pfizer products, including seven of Pfizer's nine best-selling pharmeceuticals (each of which produced more than $1 billion per year in sales).

2. Pfizer's 2004 Neurontin Settlement, the 2004 Corporate Integrity Agreement, and Pfizer's Code of Conduct

65. On May 13, 2004, Pfizer's Warner-Lambert subsidiary pled guilty to two counts of violating the FDCA, and Pfizer agreed to pay $430 million – including a $240 million criminal fine and $190 million to resolve related civil claims under the Federal False Claims Act –

to resolve government investigations and charges that Warner-Lambert, prior to its 2000 acquisition by Pfizer, illegally promoted and marketed Neurontin (an anti-convulsant) for off-label uses, and illegally provided various forms of kickbacks to healthcare providers to induce them to further prescribe Neurontin. As the DOJ then noted, the criminal fine levied upon Pfizer was the second largest criminal fine ever imposed in a health care fraud prosecution. The facts presented below help illuminate why such a large fine was merited.

66. Neurontin was FDA-indicated for (1) epileptic seizures, if used in conjunction with another drug – but not by itself ("mono-therapy"), or (2) management of specifically-delimited pain conditions in adults, namely pain resulting from shingles or herpes zoster), in (3) dosages ranging from 900 mg to 1800 mg per day. The FDA specifically rejected an application by Warner Lambert in 1997 to change Neurontin's indication and labeling to allow it to be used as a mono-therapy for epilepsy, finding that Warner-Lambert had not demonstrated Neurontin's efficacy in that role. Nor did the FDA approve prescription of Neurontin.as a general pain medication, or for treatment of various neurological conditions such as bipolar disorder, depression, migraines, and attention deficit disorder.

67. Nevertheless, Warner-Lambert systematically promoted Neurontin for off-label uses and at off-label dosages, without having established that it was medically effective or even medically safe, including: (a) mono-therapy use for epilepsy; (b) use for treatment of general pain; (c) treatment of bipolar disorder, depression, migraines, and attention deficit disorder; and (d) use at dosages exceeding 1800 mg per day.

68. A 2003 Qui Tam action initiated by a one-time Warner-Lambert medical liaison detailed in a sworn affidavit how Warner-Lambert systematically sought to boost Neurontin sales through misleading marketing/promotion for such off-label uses and through numerous forms of kickbacks to healthcare providers (including offers of paid "consultancy" engagements, paid participation in "studies", paid conference junkets at first-class hotels/resorts, and even cash payments) to induce further prescription of Neurontin for off-label uses. The scope and effect of

such widespread efforts and practices is demonstrated by the sharp increase of off-label Neurontin prescriptions during this period. For example, Neurontin prescriptions for anxiety disorders sextupled from fewer than 100,00 per year in 1999 to more than 600,000 per year in 2002 and 2003.

69. The Qui Tam allegations resulted in the federal investigation that led to Warner-Lambert's guilty plea and to Pfizer's $430 million in fines and payments. The DOJ stated that Warner-Lambert had promoted Neurontin "even when scientific studies had shown it was not effective", that Warner-Lambert agents "made false or misleading statements to health care professionals regarding Neurontin's efficacy and whether it had been approved by the FDA for off-label uses", that Warner-Lambert paid doctors to allow Warner-Lambert sales representatives to be present in patient appointments and to offer Neurontin-biased advice during such appointments, and that these and numerous other practices constituted *"a widespread, coordinated national effort to implement an off-label marketing plan*" (emphasis added).

70. In conjunction with Pfizer's May 2004 settlement of the Neurontin matter, Pfizer was required to enter into and did enter into a *second* Corporate Integrity Agreement. As the DOJ explained in announcing that agreement, the 2004 Corporate Integrity Agreement was designed to ensure that "*any future off-label marketing conduct is detected and corrected on a timely basis*" (emphasis added). To further this central purpose, the 2004 Corporate Integrity Agreement, superseding the 2002 Corporate Integrity Agreement, provided *inter alia* that:

(a) the 2004 Corporate Integrity Agreement would be operative for a five-year period;

(b) Pfizer maintain its Compliance Officer position at the senior management level throughout the term of the agreement;

(c) the Compliance Officer and Deputy Compliance Officer "make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcomittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time";

(d) Pfizer establish and maintain a "disclosure program" to enable employees to report violations of federal laws and regulations. Pfizer's Compliance Officer was required to keep a log recording (i) a summary of each disclosure receive, (ii) the status of any review, and (iii) any corrective action(s) taken in response. In order to make the program more effective in uncovering and transmitting compliance issues, Pfizer was further required to allow for "a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained", and to "emphasize a nonretribution, nonretaliation policy" with respect to employees making disclosures;

(e) Pfizer's Directors be notified, by the Compliance Officer, of Pfizer's continuing activities and obligations under the 2004 Corporate Integrity Agreement;

(f) Pfizer's Directors, Officers and employees adopt and agree to abide by a Code of Conduct (further detailed in ¶ 71 below); and

(g) Pfizer implement "written policies and procedures regarding the operation of Pfizer's Compliance Program", and that such policies and procedures must address and/or include *inter alia*: (i) that "methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products [comply] with all FDA requirements", (ii) policies designed to ensure that "consulting arrangements" and other like practices involving payments (e.g., "sponsorship", grant funding, research funding) be used only "for legitimate purposes in accordance with applicable Federal health care program requirements and FDA requirements relating to the dissemination of off-label uses of products"; and (iii) that "methods for selling, marketing and promoting Pfizer products [comply] with all applicable Federal health care program requirements, including but not limited to, the Federal anti-kickback statute".

71. In conjunction with the 2004 Corporate Integrity Agreement, as adverted to above, Pfizer was required to establish, adopt and abide by a Code of Conduct. Pfizer agreed that its Code of Conduct would state explicitly that all Pfizer officers and employees were expected to comply with all Federal health care program requirements and FDA requirements, and that Pfizer Officers involved in U.S. pharmaceutical operations would certify that they "read, received,

understood and shall abide by" the Code of Conduct, including the above-mentioned compliance requirement.

72. The Code of Conduct adopted by Pfizer's Directors further, and explicitly, involved them in the issue of Pfizer's compliance. Pfizer's Directors were required, by the Code of Conduct, to "comply, and oversee compliance by employees, officers and other directors with laws, rules, and regulations applicable to the Company".

73. Notwithstanding the Corporate Integrity Agreements and the numerous positions, procedures and policies they established within Pfizer to inform the Board of compliance misconduct (*e.g.*, the at-least semi-annual reports by and meetings with the Compliance Officer, the Compliance's Officer's authority to provide further compliance reports on an *ad hoc* and as- needed basis, the "disclosure program" and its various protections of nonretaliation and anonymity, and the Compliance Offer's record-keeping burden with respect to misconduct disclosures received and actions/investigations taken) and thus allow the Board to exercise compliance oversight, and notwithstanding the further compliance obligations Pfizer Officers and Directors adopted through the Code of Conduct, the Director Defendants and the Officer Defendants allowed Pfizer to continue to engage in long-standing, illegal promotional, marketing and sales misconduct throughout the Relevant Period with respect to numerous (at least thirteen) Pfizer products, including seven of Pfizer's nine best-selling pharmaceuticals (each of which produced more than $1 billion per year in sales).

3. Pfizer's 2007 Genotropin Settlement and the 2007 Deferred Prosecution Agreement

74. On March 27, 2007, Pfizer payed a $35 million fine, Pfizer's Pharmacia subsidiary entered into a criminal guilty plea, and Pfizer entered into a deferred prosecution agreement, all relating to illegal promotion and sales practices of the Genotropin drug for off-label uses, in violation of the FDCA and the Federal anti-kickback statute.

75. Genotropin, a human growth hormone, is indicated for treating children who suffer from growth failure. As Pfizer's Pharmacia subsidiary admitted in its guilty plea, however,

Pharmacia promoted and marketed Genotropin for a wide range of other off-label uses not approved by the FDA, including as a steroid for athletic performance enhancement, as an anti-aging treatment/cosmetic treatment (*e.g.*, to produce better skin tone or skin elasticity, etc.), through *inter alia* visiting anti-aging doctors and clinics and providing misleading information about Genotropin's efficacy. The guilty plea also contained admissions of providing kickbacks, in criminal violation of the Federal anti-kickback statute, of providing excess payments to a drug distribution company to induce greater purchases of Pharmacia products.

DEFENDANTS BREACHED THEIR FIDUCIARY DUTIES BY CONSCIOUSLY DISREGARDING AND/OR AFFIRMATIVELY CONDONING PFIZER'S LONG-STANDING, PERVASIVE, AND ILLEGAL MARKETING, PROMOTION AND SALE OF NUMEROUS PFIZER PRODUCTS FOR OFF-LABEL USES AND VIA NUMEROUS FORMS OF KICKBACKS, CAUSING PFIZER TO INCUR SUBSTANTIAL COSTS, DAMAGES AND RECORD-BREAKING FINES

76. As detailed below, at various times during and/or throughout the Relevant Period, Pfizer: (1) illegally promoted four drugs – Bextra (an anti-inflammatory); Geodon (an anti-psychotic drug); Zyvox (an antibiotic); and Lyrica (an anti-epileptic drug) – for off-label uses, and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs; and (2) paid kickbacks to health care providers to induce them to prescribe these four drugs, as well as nine others, namely, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec.

77. Nothwithstanding their general fiduciary duties to Pfizer and its shareholders, and notwithstanding their heightened duties with respect to regulatory compliance arising from prior regulatory misconduct and the 2002 Corporate Integrity Agreement, 2004 Corporate Integrity Agreement, and Code of Conduct to which such misconduct gave rise – all of which focused Pfizer's officers and directors on their responsibilities for compliance oversight, and all of which operated to establish positions, policies and procedures to uncover regulatory misconduct and report such misconduct to Pfizer's Board – Defendants instead *continued* to cause the Company to engage in widespread marketing and promotion of numerous Pfizer pharmaceuticals for off-label uses and to stimulate sales and prescriptions of numerous Pfizer pharmaceuticals through numerous forms of

illegal kick-backs.

78. Pfizer's continuing misconduct was not merely massive and long-standing, involving at least thirteen different Pfizer pharmaceuticals during the Relevant Period, including seven of Pfizer's nine best-selling drugs, but it was *recidivist* (the term used by federal regulators[1]): it involved the very same practices (off-label marketing, promotion and sales; kickbacks) for which Pfizer had repeatedly been punished (the above-mentioned Lipitor, Neurontin and Genotropin affairs) and which Defendants therefore well knew violated federal laws and regulations.

79. This continuing misconduct ultimately caused Pfizer to incur $2.3 billion in criminal fines, forfeitures and civil payments to federal regulators (including, as the DOJ noted, "the largest criminal fine ever imposed in the U.S. for any matter"), exposed Pfizer to substantial further legal exposures, costs and liabilities (for which Pfizer has already incurred further charges of nearly $1 billion), and substantially diminished Pfizer's reputation and goodwill, especially among regulators, who – if faced with further misconduct by Pfizer – hold the "nuclear option" of excluding Pfizer from participation in federally-funded healthcare programs such as Medicaid and Medicare (the largest purchasers of prescription drugs).

80. As the DOJ explained in a September 2, 2009 release announcing the criminal fines, forfeitures and civil payments levied upon Pfizer, the record-breaking size of Pfizer's fines and payments was calibrated to match the degree of offense. Pfizer's regulatory violations were not merely longstanding (continuing throughout the Relevant Period), and not merely pervasive (involving at least thirteen drugs, including seven of Pfizer's nine best-sellers), but brazenly recidivist (in that, at the very same time Pfizer was negotiating settlements with federal regulators over such illegal practices with respect to three different drugs, it continued to employ the very same practices with respect to at least thirteen more):

"The size and seriousness of this resolution, including the huge

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[1] *See*, *e.g.*., Gardiner Harris, *Pfizer Pays $2.3 Billion to Settle Marketing Case*, New York Times, Sept. 3, 2009 ("Among the factors we considered in calibrating this severe punishment was Pfizer's recidivism," said Michael K. Loucks, acting United States attorney for the Massachusetts district").

> criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

A. Pfizer's Off-Label Promotion and Marketing of Bextra, Geodon, Zyvox and Lyrica

81. **Bextra**. Between February 2002 and April 2005 (when Bextra was withdrawn from the market), Pfizer promoted and marketed Bextra – a non-steroidal anti-inflammatory drug ("NSAID") indicated and FDA-approved in low dosages for osteoarthritis, adult rheumatoid arthritis, and primary dismennorhea (severe uterine pain during menstruation) – for far wider and far more general off-label uses, including general treatment of acute pain, and treatment of various types of post-surgical pain, and at dosages above the approved maximum. As announced on September 2, 2009, Pfizer's Pharmacia subsidiary pled guilty to a criminal felony charge of violating the FDCA and admitted that it intentionally, with intent to deceive and defraud, marketed and promoted Bextra for off-label uses and at off-label dosages that had not been approved by the FDA.

82. Pfizer's conduct with regard to Bextra –detailed below – caused significant harm to Pfizer: of the $2.3 billion of costs and fines and payments incurred as a result of the September 2009 settlement, at least $1.3 billion was attributable to Pfizer's off-label marketing of Bextra, including a $1.195 billion criminal fine for illegal, off-label marketing and promotion of Bextra, and a further forfeiture of $105 million to settle such criminal charges. As regulators explained, the unprecedented size of the fine levied upon Pfizer for its conduct with respect to Bextra, stemmed from the twin facts that: (1) at the time it marketed and promoted Bextra for numerous off-label uses, and at dosages higher than those approved by the FDA, Pfizer knew that Bextra was dangerous and especially so in higher dosages (as the DOJ explained on September 2,

2009, "Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns"); and (2) that Pfizer's Bextra-related misconduct was not only long-standing and pervasive (as the government's prosecuting attorney explained, "Pfizer violated the law over an extensive period of time"), but condoned and tolerated by numerous senior personnel throughout the Company (as an August 31, 2009 letter from the government's prosecuting attorney to Pfizer's counsel stated concerning calculation of the fine, "an individual within the high level personnel of the unit participated in or condoned the offense and/or tolerance of the offense by substantial authority personnel was pervasive throughout the organization").

83. In 2001, Pfizer's Pharmacia subsidiary (then an independent company) sought Bextra's indication for treatment of acute pain and dismenorrhea at dosages of 40 mg per day, and for treating arthritis at dosages of 10-30 mg per day. The FDA denied this request in November 2001, specifically rejecting Bextra's use for acute pain and post-operative pain after finding that 40 mg dosages "demonstrated an excess of serious adverse events including death". These in turn were associated with an increased risk presented by Bextra of blood clot formation (despite the fact that patients taking Bextra were simultaneously taking blood-thinning medication), which carries the risk of producing heart attack (when blood clots reach the heart), stroke (when blood clots reach the brain), or pulmonary embolism (when blood clots reach the lungs). As a result, the FDA approved Bextra only at 10 mg per day for arthritis and 20 mg for dismenorrhea. The FDA communicated its findings and conclusions to Pharmacia, emphasizing such safety concerns, and putting Pharmacia on notice that dosages of Bextra exceeding 20 mg/day were dangerous, and off-label uses unwarranted especially given the dangers at such dosages.

84. Notwithstanding these *ab initio* concerns and limitations on Bextra's indicated use, Pharmacia and Pfizer (which, though it acquired Pharmacia in 2003, joined an alliance with Pharmacia in 2002 to jointly market Bextra and Celebrex) engaged in widespread, constant efforts to market and promote Bextra for off-label uses and for use in off-label dosages, including numerous misleading representations as well as numerous kickback schemes. As detailed in the Pfizer's

settlement with the government, and numerous whistle-blower actions, the misconduct occurred via:

(a) Headquarter Marketing Plans: Pharmacia's and Pfizer's marketing teams positioned Bextra for acute pain, surgical pain, and other unapproved uses and dosages, commissioned market research to test its sales materials, and confirmed these unapproved messages. In such documents, Pharmacia's and Pfizer's marketing teams stated as the "intended" use and message for Bextra that Bextra was for "acute pain." Indeed, a March 2002 presentation authored by Pharmacia's legal division, only months after the FDA rejection of an acute pain indication for Bextra, stated that Bextra would "pursue" Bextra's use for acute pain and that the "positioning message" for Bextra would be "Meet All Arthritic and Pain Relief Needs";

(B) Field Force Implementation: Pharmacia's and Pfizer's sales forces promoted Bextra directly to physicians for these unapproved uses and dosages, including by drafting and distributing proposed physician standing orders and hospital wide protocols and pain pathways that called for unapproved uses of Bextra. The sales forces also made false and misleading claims to physicians about Bextra's safety and efficacy;

(c) Payments and Other Remuneration to Physicians/Purported Consultants: Pharmacia and Pfizer used so-called advisory boards, consultant meetings and other remuneration, including travel to lavish resorts, to promote Bextra to medical prescribers for unapproved uses and dosages and with false and misleading claims as to its safety and efficacy. Between late 2001 and 2003, Pharmacia held nearly 100 consultant meetings to promote unapproved uses and dosages of Bextra, in the process entertaining over 5,000 healthcare providers and professionals;

(d) Sham Physician Requests for Off-Label Information: Pharmacia's and Pfizer's sales forces created sham physician requests for medical information in order to send unsolicited information to physicians about unapproved uses and dosages;

(e) Distributing Samples for Unapproved Uses and Dosages: Pharmacia and Pfizer provided promotional samples to surgeons and other medical prescribers who had no FDA-approved use for the Bextra samples, or at that dosage;

(f) Control of Purportedly Independent Medical Education ("CME"): Pharmacia and Pfizer sponsored purportedly independent CME to disseminate messages about unapproved uses of Bextra, including for acute and surgical pain; and

(g) Use of a Publication Strategy to Disseminate Off-label Messages: Pharmacia and Pfizer initiated and paid vendors to draft articles about Bextra for unapproved uses without appropriate disclosures of Pharmacia/Pfizer's role.

85. Bextra was one of a class of drugs known as "Cox-2 inhibitors", which also included Vioxx and Celebrex, all of which carried similar cardiovascular issues and risks (*i.e.*, associated at various dosages with blood clot formation and the potential adverse and/or lethal consequences of such clotting). In September 2004, Vioxx's sponsor Merck agreed to remove Vioxx from the market after a clinical trial demonstrated increased risk of exactly such serious adverse consequences (hearth attack, stroke) associated with prolonged Vioxx use. In response, European medical regulators announced an immediate review of "cardiovascular safety for all licensed COX-2 inhibitors", including Bextra. Nearly simultaneously, a study of Bextra's joint use together with another Pfizer drug, parecoxib, in coronary artery bypass graft surgery, demonstrated a statistically significant association with like negative cardiovascular outcomes.

86. On January 10, 2005, the FDA's Division of Drug Marketing, Advertising and Connunication ("DDMAC") sent a letter to Pfizer's vice-president of regulatory affairs alerting Pfizer that certain of its marketing and promotional materials for Bextra were misleading, particularly with respect to the dangers of Bextra's side-effects. Though Bextra's marketing materials proclaimed that the "Bextra provides significant protection from serious GI [gastro-intestinal] side effects", the FDA's letter concluded that "these safety claims are inconsistent with the Warning in the Bextra PI regarding serious and life-threatening GI side effects, including bleeding in the stomach and intestines".

87. After meeting with Pfizer and other sponsors of COX-2 drugs in January 2005 to discuss the drugs' safety issues, the European Medicines Agency ("EMA") on February 17, 2005

announced its conclusion that COX-2 inhibitors, as a class, resulted in increased risk of negative cardiovascular events, and recommended that doctors, to the extent they use COX-2 inhibitors at all, "use the lowest effective does for the shortest possible duration".

88. Notwithstanding the *ab initio* safety concerns communicated by the FDA in 2001, and that led the FDA to delimit Bextra's indications, Pharmacia and Pfizer continued to promote and market Bextra for off-label uses at unapproved dosages thereafter until April 2005, and continued to do so during late 2004 and early 2005 as safety concerns mounted. On or about April 7, 2005, the FDA requested that Pfizer withdraw Bextra from the market after determining it to be "associated with an increased risk of serious adverse events in two short term trials".

89. **Geodon**. Nearly throughout the Relevant Period, between January 2001 and December 2007, Pfizer promoted and marketed Geodon – an antipsychotic initially approved for treating acute manifestations of schizophrenia, and later expanded to include acute manic or mixed episodes associated with bipolar disorder – for a far wider variety of off-label uses with far greater patient populations, including, inter alia: depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism, and post-traumatic stress disorder. Furthermore, Pfizer promoted and marketed Geodon for treatment of patient populations that had not been approved by the FDA, including pediatric and adolescent patients, and in dosages above approved maximum. Such practices violated FDCA provisions against off-label marketing, promotion and sale, and constituted false claims upon the government in that Medicaid programs provided funding/reimbursement for Geodon's use for not-medically-accepted indications.

90. Concurrently, Pfizer made and/or disseminated unsubstantiated and/or false representations about Geodon's safety and efficacy. And, as noted in ¶ 101, below, Pfizer also offered and provided various illegal kickbacks to healthcare providers and professionals to induce further Geodon prescriptions and sales, including – as detailed in whistle-blower actions – the establishment of sponsored promotion speaker programs to present off-label Geodon uses. These

events included direct promotion by Pfizer sales representatives, as well as hiring of physicians to give promotional talks to other doctors about Geodon's off-label uses.

91. The Geodon matter is noteworthy insofar as Pfizer continued actively to mislead and promote Geodon's off-label uses despite being receiving at least two warning letters from the FDA (dated September 3, 2002 and July 16, 2007) informing Pfizer that its Geodon marketing and promotions were both misleading and illegal in that they: (a) misleadingly suggested that Geodon was safer than actually demonstrated, and omitted important risk information; (b) contained unsubstantiated superiority claims over competing products; and (c) improperly and illegally promoted Geodon for treatment of depresssion – an off-label use.

92. Despite these red flags presented to Pfizer by regulators adverting to Pfizer's misleading and off-label Geodon promotions, Pfizer continued to promote Geodon nearly throughout the Relevant Period by improper and illegal means, including marketing and promotion for widespread off-label uses and via kickback schemes. Allegations in whistle-blower complaints show that, shortly after having received the September 3, 2002 FDA letter alerting Pfizer that it was improperly marketing Geodon for off-label uses, Pfizer's top-down and explicit sales policy for Geodon (stated by the national head of Geodon marketing) was to promote Geodon use beyond its indicated market.

93. This conduct caused significant harm to Pfizer: of the $2.3 billion of costs and fines and payments incurred as a result of the September 2009 settlement, $301 million was attributable to Pfizer's off-label marketing of Geodon.

94. **Zyvox**. Nearly throughout the Relevant Period, between January 2001 and February 2008, Pfizer promoted and marketed Zyvox – an antibiotic indicated and FDA-approved for Vancomycin-Resistant Enterococcus faecium infections, nosocomial pneumonia, community-acquired pneumonia, and complicated skin and skin structure infections (including diabetic foot infections without concomitant osteomyelitis) – for wider off-label use as a general treatment for infections caused by methicillin-resistant Staphylococcus aureus ("MRSA"), rather

than only those types of MRSA infections for which Zyvox was FDA-approved. Such practices violated FDCA provisions against off-label marketing, promotion and sale, and constituted false claims upon the government in that Medicaid programs provided funding/reimbursement for Zyvox's use for not-medically-accepted indications.

95. Concurrently, Pfizer made and/or disseminated unsubstantiated and/or false representations about Zyvox's safety and efficacy, including that Zyvox was superior to its primary competitor for such indications, Vancomycin. And, as noted in ¶ 101, below, Pfizer also offered and provided various illegal kickbacks to healthcare providers and professionals to induce further Zyvox prescriptions and sales.

96. The Zyvox matter is noteworthy insofar as Pfizer admitted, in connection with Pfizer's 2009 settlement, that it continued actively to mislead and promote off-label uses with respect to Zyvox despite being notified by a July 20, 2005 warning letter from the FDA to Defendant McKinnell (then Pfizer's Chairman and CEO) that Pfizer's Zyvox marketing and promotion was both misleading and illegal in that it: (a) implied superiority over a competing product, Vancomycin, without basis in substantive evidence; (b) failed to provide important risk information; and (c) improperly and illegally broadened the scope of Zyvox usage.

97. Although Pfizer agreed after receiving the July 20, 2005 FDA letter to discontinue such marketing and promotions, and to publish a correction, Pfizer admitted that in fact it did not discontinue such marketing and promotions, and instead continued to promote and market Zyvox in manners already-identified as false, misleading and illegal. Pfizer admitted that it "did not provide adequate guidance to its sales force regarding what statements were permissible" and that, resultingly, "Pfizer's sales personnel thereafter continued to make [unsubstantiated superiority/efficacy] claims to physicians that Zyvox was superior to vancomycin for MSRA. . . despite the fact that these claims were inconsistent with the FDA's Warning Letter and Zyvox's FDA approved label. . .".

98. Such admitted facts as to continued misconduct even in the presence of "red flags" presented by regulators to Pfizer's most senior officer and director (i.e., Pfizer's CEO and Chairman) strongly support Defendant's culpability here, as well as demand futility. Nor was this an isolated instance. These admitted facts are further supported by a host of related allegations in eleven various whistle-blower complaints, including allegations that Pfizer instructed Zyvox sales representatives to contact vascular surgeons to promote Zyvox despite the fact that such practictioners would have little or no reason to use Zyvox for its indicated use.

99. **Lyrica**. Between September 2005 and October 2008, Pfizer illegally promoted and marketed Lyrica – indicated and FDA-approved for management of post-herpetic neuralgia, management of neuropathic pain associated with diabetic peripheral neuropathy, and fibromyalgia – for a far wider variety of off-label uses, including management of chronic pain, neuropathic pain, perioperative pain, and migraine, with far-larger patient markets. Such practices violated FDCA provisions against off-label marketing, promotion and sale, and constituted false claims upon the government in that Medicaid programs provided funding/reimbursement for Lyrica's use for not-medically-accepted indications.

100. Concurrently, Pfizer directed its sales representatives to disseminate false, misleading and unsubstantiated representations that Lyrica was more effective than competitor drugs for such uses, despite the absence of studies so showing. And, as noted in ¶ 101, below, Pfizer also offered and provided various illegal kickbacks to healthcare providers and professionals to induce further Lyrica prescriptions and sales.

B. Pfizer's Provision of Kickbacks to Induce Further Drug Prescription of At Least Thirteen Different Pfizer Drugs

101. As disclosures accompanying Pfizer's 2009 settlement made clear, between at least 2001 and 2004, Pfizer provided various forms of kickbacks – including, *inter alia*, "gifts" (such as cash payments, and payments for entertainment, travel, lodging, and meals), and illegal remuneration routed through various "shells" such as speaker programs and mentorships – to induce

health care providers and professionals to further prescribe at least thirteen Pfizer products (Bextra, Geodon, Zyvox, Lyrica, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft, and Zyrtec), thereby (1) violating the Federal anti-kickback statute, and (2) causing false claims to be submitted to federal health care programs such as Medicaid.

C. The Director Defendants' Duties and Their Failure to Properly and Adequately Discharge Their Duties

1. General Fiduciary Principles and Duties

102. By reason of their positions as officers, directors, and/or fiduciaries of Pfizer, and because of their ability to control the business and corporate affairs of Pfizer, Defendants owed Pfizer and its shareholders fiduciary obligations of good faith, loyalty and candor, and were and are required to use their utmost ability to control and manage Pfizer in a fair, just, honest and equitable manner. Defendants were and are required to act in furtherance of the best interests of Pfizer and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit. Each director and officer of Pfizer owes to Pfizer and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

103. Defendants, because of their positions of control and authority as directors and/or officers of Pfizer, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein. Because of their advisory, executive, managerial, and directorial positions with Pfizer, each of the Defendants had knowledge of material non-public information regarding the Company.

104. To discharge their duties, the officers and directors of Pfizer were required to excercise reasonable and prudent supervision over the management, policies, practices and controls of the Company. By virtue of such duties, the officers and directors of Pfizer were required to, among other things:

(a) Exercise good faith to ensure that the affairs of the Company were conducted

in an efficient, business-like manner so as to make it possible to provide the highest quality performance of their business;

(b) Exercise good faith to ensure that the Company was operated in a diligent, honest and prudent manner and complied with all applicable federal and state laws, rules, regulations and requirements, and all contractual obligations, including acting only within the scope of its legal authority; and

(c) When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence.

2. Further Duties Imposed on Defendants By Virtue of Pfizer's Code of Conduct

105. The Director Defendants, since at least 2004 and as part of the 2004 Corporate Integrity Agreement occasioned by prior misconduct involving off-label marketing and promotion, adopted and agreed to abide by Pfizers's Code of Business Conduct and Ethics. With respect to directors and the Director Defendants, the Code of Conduct placed the issue of regulatory compliance squarely in the Director Defendants' purview, providing that "Directors must comply, and oversee compliance by employees, officers and other directors with all laws, rules, and regulations applicable to the Company".

106. Additionally, pursuant to the Code, directors and the Director Defendants were required to encourage the reporting of any illegal or unethical behavior, including taking steps to ensure that Pfizer informs employees that Pfizer will not allow retaliation for reports made in good faith.

107. Likewise, with respect to Pfizer's officers and the Officer Defendants, Pfizer agreed that its Code of Conduct would state explicitly that all Pfizer officers and employees were expected to comply with all Federal health care program requirements and FDA requirements, and that Pfizer officers involved in U.S. pharmaceutical operations would certify that they "read, received, understood and shall abide by" the Code of Conduct, including the above-mentioned

compliance requirement.

3. Further Duties Imposed on the Audit Committee Defendants and the Corporate Governance Committee Defendants By Virtue of Their Board Committee Memberships and Responsibilities

108. Pursuant to the Audit Committee's Charter, members of the Audit Committee and the Audit Committee Defendants are and were required, *inter alia*, to:

(a) Review the status of compliance with laws, regulations, and internal procedures;

(b) Review the scope and status of systems designed to promote Company compliance with laws, regulations and internal procedures;

(c) Review contingent liabilities and risks that may be material to the Company; and

(d) Review major legislative and regulatory developments which could materially impact the Company's contingent liabilities and risks.

109. Pursuant to the Corporate Governance Committee's Charter, the members of the Corporate Governance Committee and the Corporate Governance Committe Defendants are and were required*, inter alia*, to:

(a) Consider matters of corporate governance; and

(b) Maintain an informed status on Company issues related to corporate social responsibility.

4. Further Duties Imposed on Defendants by Prior Misconduct, the 2002 and 2004 Corporate Integrity Agreements, and Positions, Policies and Mechanisms Established by Those Agreements to Uncover and Report Regulatory Misconduct to Senior Management and Pfizer's Board

110. As already detailed, between 2002 and 2007 Pfizer was engaged in three separate regulatory investigations/settlements involving, with respect to three drugs, the very sorts of regulatory misconduct that Pfizer contemporaneously continued to engage in with respect to thirteen more drugs. Defendants were therefore aware that the misconduct at issue here was in fact misconduct, and that such misconduct could subject Pfizer to substantial regulatory, financial and

reputational consequences.

111. More: as a result of such misconduct, Pfizer was required to enter into Corporate Integrity Agreements in both 2002 and 2004. These agreements were designed, as the DOJ explicitly stated, to ensure that "*any future off-label marketing conduct is detected and corrected on a timely basis*" (emphasis added). To further this central purpose, the 2002 and 2004 Corporate Integrity Agreements, provided *inter alia* that:

(a) the 2002 Corporate Integrity Agreement would be operative for five years; though superseded by the 2004 Corporate Integrity Agreement which itself would be operative for a five-year period;

(b) Pfizer establish (2002 Agreement) and maintain (2004 Agreement) its Compliance Officer position at the senior management level throughout the term of the agreement;

(c) the Compliance Officer and Deputy Compliance Officer "make periodic (at least semi-annual) reports regarding compliance matters directly to the Board of Directors of Pfizer (or its designated subcomittee, in such form or manner as the Board of Directors determines), and both shall be authorized to report on such matters to the Board of Directors at any time";

(d) as per the 2004 Agreement, Pfizer establish and maintain a "disclosure program" to enable employees to report violations of federal laws and regulations. Pfizer's Compliance Officer was required to keep a log recording (i) a summary of each disclosure receive, (ii) the status of any review, and (iii) any corrective action(s) taken in response. In order to make the program more effective in uncovering and transmitting compliance issues, Pfizer was further required to allow for "a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained", and to "emphasize a nonretribution, nonretaliation policy" with respect to employees making disclosures;

(e) Pfizer's Directors be notified, by the Compliance Officer, of Pfizer's continuing activities and obligations under the 2004 Corporate Integrity Agreement;

(f) per the 2004 Agreement, Pfizer's Directors, Officers and employees adopt and

agree to abide by a Code of Conduct; and

(g) per the 2004 Agreement, Pfizer implement "written policies and procedures regarding the operation of Pfizer's Compliance Program", and that such policies and procedures must address and/or include *inter alia*: (i) that "methods for selling, marketing, promoting, advertising, and disseminating information about off-label uses of Pfizer's products [comply] with all FDA requirements", (ii) policies designed to ensure that "consulting arrangements" and other like practices involving payments (e.g., "sponsorship", grant funding, research funding) be used only "for legitimate purposes in accordance with applicable Federal health care program requirements and FDA requirements relating to the dissemination of off-label uses of products"; and (iii) that "methods for selling, marketing and promoting Pfizer products [comply] with all applicable Federal health care program requirements, including but not limited to, the Federal anti-kickback statute".

112. Notwithstanding the Corporate Integrity Agreements and the numerous positions, procedures and policies they established within Pfizer to inform the Board of compliance misconduct (*e.g.*, the at-least semi-annual reports by and meetings with the Compliance Officer, the Compliance's Officer's authority to provide further compliance reports on an *ad hoc* and as- needed basis, the "disclosure program" and its various protections of nonretaliation and anonymity, and the Compliance Offer's record-keeping burden with respect to misconduct disclosures received and actions/investigations taken) and thus allow the Board to exercise compliance oversight, and notwithstanding the further compliance obligations Pfizer Officers and Directors adopted through the Code of Conduct, the Director Defendants and the Officer Defendants allowed Pfizer to continue to engage in long-standing, illegal promotional, marketing and sales misconduct throughout the Relevant Period with respect to numerous (at least thirteen) Pfizer products, including seven of Pfizer's nine best-selling pharmaceuticals (each of which produced more than $1 billion per year in sales).

5. Further Duties Imposed on Defendants by Virtue of Numerous "Red Flags" Evidencing or Adverting to Regulatory Misconduct

113. The above-mentioned features of the Corporate Integrity Agreements were

designed to and functioned to bring reports on regulatory compliance misconduct and noncompliance to the attention of the Compliance Officer (from 2002 through 2006, Defendant Kindler) and the Board, through (1) the regular and/or *ad hoc* compliance reports from and meetings with the Compliance Officer), (2) the "disclosure program" that channeled employee reports of noncompliance to the Compliance Officer and through him to the Board, and (3) emphasizing the Board's oversight role in ensuring compliance.

114. Pursuant to these policies, procedures and mechanisms, the Board and the Director Defendants were repeatedly informed during the Relevant Period of allegations of regulatory misconduct with respect to pharmaceutical marketing, promotion and sales.

115. Furthermore and in addition, Pfizer received and the Board and the Director Defendants were informed of, numerous "red flags" – often presented by regulators – informing or adverting to specific yet repeated and similar instances of regulatory misconduct, especially off-label marketing and promotion. These red flags included:

(a) The September 3, 2002 FDA Warning Letter regarding Pfizer's misleading promotion and marketing of Geodon (¶ 91, *supra*);

(b) 2003 reports, from Pfizer employee Blair Collins (who filed a whistle-blower action in 2004) to Pfizer's compliance personnel, of kickbacks and violation of anti-kickback statute violations relating to Glucotrol, Lipitor, Norvasc, Viagra, Zithromax, Zoloft and Zyrtec;

(c) Pfizer's 2004 settlement of off-label promotion and marketing violations relating to Neurontin (¶¶ 69-71, *supra*);

(d) 2004 reports, from Pfizer employee Glenn Demott (who filed a whistle-blower action in 2005) to Pfizer's compliance office, of misleading promotional and marketing materials;

(e) The FDA's January 10, 2005 letter regarding misleading promotional/marketing materials for Bextra (¶ 86, *supra*);

(f) The July 20, 2005 FDA Warning Letter sent to Pfizer's Chairman and CEO (Defendant McKinnell) alerting Defendants to regulatory misconduct relating to Zyvox, including

misleading promotional/marketing materials and promoting/marketing Zyvox for off-label uses (¶ 96, *supra*);

(g) 2006 reports, from Pfizer employee Robert Liter to Pfizer compliance personnel and corporate counsel, concerning illegal off-label promotion of Lyrica;

(h) 2006-2007 reports, from Pfizer employees David Farber and Casey Schildhauer (who filed a whistle-blower action in 2007) to Pfizer management, concerning illegal off-label promotion of Lyrica;

(i) 2006-2007 reports, from Pfizer employee Mark Westlock (who filed a whistle-blower action in 2008) to Pfizer compliance personnel, human resources personnel, Pfizer regional and district managers, and Pfizer's president of U.S. pharmaceutical operations (*i.e.*, Defendant Read), concerning illegal off-label promotion of Geodon;

(j) Pfizer's 2007 settlement of off-label promotion and marketing violations relating to Genotropin (¶¶ 74-75, *supra*);

(k) The FDA's July 16, 2007 letter regarding misleading promotional/marketing materials for Geodon (¶ 91, *supra*);

(l) The 2008 whistle-blower action filed by Pfizer district manager Ronald Rainero concerning illegal off-label promotion of Zyvox; and

(m) An April 16, 2008 FDA Warning Letter sent to Pfizer Chairman and CEO (Defendant Kindler) informing of misleading promotional and marketing materials for Viagra.

116. These specific yet repetitive "red flags", waived both by company insiders and regulatory outsiders, imposed in and of themselves, by virtue of their cumulative heft, a substantial duty upon Defendants to investigate and act to correct or halt such widespread and evergreen misconduct. This duty anyway existed by virtue of Defendants' positions as officers and/or directors, and by virtue of the Code of Conduct to which Defendants agreed to abide – and existed in yet heightened fashion for the Audit Committee Defendants and the Corporate Governance Committee Defendants.

117. Defendants failed utterly to discharge these duties.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

118. Plaintiff brings this action derivatively in the right and for the benefit of Pfizer to redress the breaches of fiduciary duty and other violations of law by the Defendants as alleged herein.

119. Plaintiff will adequately and fairly represent the interests of Pfizer and its shareholders in enforcing and prosecuting its rights.

120. Pfizer's Board currently consists of fourteen individuals, including thirteen Director Defendants (Ausiello, Brown, Burns, Burt, Cornwell, Gray, Horner, Johnson, Kilts, Kindler, Lorch, Mead and Steere) together with non-party Pfizer director Stephen Sanger (who became a Pfizer director only recently, in February 2009). Plaintiff did not make a demand upon the Pfizer Board to institute this action to recover damages suffered by Pfizer, because doing so would be futile. Detailed facts pleaded herein and re-presented below demonstrate that none of the Director Defendants can properly consider demand, and that a majority of the current Board members lack sufficient independence and necessary disinterest either *de jure* (inside executives Kindler and Steere) or *de facto* (Ausiello, Brown, Burns, Burt, Cornwell, Gray and Horner: all of whom, as Audit Committee Defendants or Corporate Governance Committee Defendants, served on Board Committees during the Relevant Period that imposed heightened duties to identify and correct the misconduct alleged herein, and whose failures to act in a manner corresponding to such duties thus give rise to a substantial likelihood of liability for their breaches of fiduciary duty).

A. The Director Defendants Consistently Acted in Dereliction of Their Duties, In Bad Faith, and Without Exercise of Business Judgment, in Consciously Disregarding and/or Affirmatively Condoning Pfizer's Illegal Misconduct, Off-Label Marketing, and Kickbacks

121. Pfizer's operational misconduct was widespread and longstanding. Pfizer's 2009 settlement involved misconduct relating to thirteen different drugs – including seven of Pfizer's nine best-selling pharmaceuticals – over a period of nearly eight years.

122. During this time, the Director Defendants were repeatedly presented with facts

alerting them of the relevant misconduct: illegal sales and promotion practices, including the promotion of off-label uses and dosages, dissemination of false and misleading information to induce doctors into prescribing Pfizer's drugs, and offers remuneration to doctors who did prescribe Pfizer drugs (as detailed above at ¶¶ 110-115, *supra*).

123. During this time, each of the Director Defendants knew that they had a duty to monitor and ensure Pfizer's compliance with FDA requirements, Federal healthcare program requirements and the Federal anti-kickback statute (as detailed above at ¶¶ 105-112, *supra*). Such duties arose not merely from their position as Directors and not merely from the materiality of such compliance (particularly with respect to Pfizer's best-selling pharmaceutical products), but also from: (a) Pfizer's Code of Business Conduct and Ethics, which, for Directors, specifically charged the Director Defendants with overseeing compliance (¶¶ 105-107 *supra*); and (b) the Corporate Integrity Agreements, which (i) also emphasized the Director Defendants' role in overseeing and monitoring compliance, specifically with respect to illegal, off-label marketing/promotion of Pfizer drugs, and which (ii) required Pfizer's Compliance Officer to report on Pfizer's compliance "directly to the Board of Directors" or to the Board's designated subcommittee at least semi-annually and as often as "any time" compliance matters arose, as well as to inform the Board about reports from employees under the disclosure program that employees were violating federal regulations (¶¶ 110-111 *supra*).

124. Despite being informed of numerous red flags that numerous Pfizer employees were engaging in illegal sales and promotional practices, the Director Defendants – and especially the Audit Committee Defendants and the Corporate Governance Committee Defendants (as further detailed in ¶¶ 127-137, *infra*) – consciously disregarded their responsibility to act.

125. Given the pervasiveness and consistency of the misconduct, Defendants' responsibility for overseeing and monitoring compliance and their awareness of the same, and the numerous compliance reporting mechanisms and actual reporting instances of non-compliance that were designed to and did convey compliance issues to Defendants and the Board, the Director

Defendants either: (a) knowingly chose not to address the pervasive misconduct detailed herein, including off-label marketing and promotion and illegal sales practices, in intentional breach and/or conscious disregard of their fiduciary duties; or (b) affirmatively approved, condones and/or directed that very misconduct, which subjected Pfizer to the largest government fine in history.

126. Accordingly, the Director Defendants' actions in directing, permitting, or otherwise failing to prevent the consistent, widspread misconduct detailed herein permits only two conclusions. First, and seen in the best light: a sustained and systematic failure of the Board to exercise oversight, based on conscious, constant disregard of red flags. Or, second: Board approval of a Pfizer business strategy/culture focused on increasing short-term growth and income by illegal and highly risky means. Either way, the result is the same: that Defendants or a majority of them did not act in good faith, and/or that their conduct was not a valid exercise of business judgment. A prior demand upon the Director Defendants that they commence this action is therefore excused.

B. A Majority of Pfizer's Current Directors Face A Substantial Likelihood of Liability for Condoning or Consciously Disregarding Pfizer's Long-Standing and Pervasive Misconduct

127. Though evidence of such misconduct was repeatedly presented to Defendants, and though multiple monitoring structures were established to convey such information to the Director Defendants, the misconduct not only continued for years but was applied pervasively throughout Pfizer, affecting *inter alia* seven of Pfizer's nine best-selling, most important pharmaceutical products. A majority of Pfizer's current directors – particularly, as discussed herein, those who served on Pfizer's Audit Committee and Corporate Governance Committee – face a substantial likelihood of liability due to their conscious disregard (or approval) of the misconduct detailed herein. They therefore cannot be considered disinterested and/or independent for purposes of satisfying demand futility, and are thus disabled from properly considering demand.

128. **Defendants Kindler and Steere**. There is no controversy as to Kindler's and Steere's lack of independence; Pfizer's Board itself admits it:

With the assistance of legal counsel to the Company, the Corporate

> Governance Committee has reviewed the applicable legal standards for Board and Board committee member independence... The Board has also determined that Messrs. Jeffrey B. Kindler and William C. Steere, Jr. are not independent under these Standards. Mr. Kindler is not considered an independent Director because of his employment as Chairman and Chief Executive Officer of the Company. Mr. Steere is not considered an independent Director as a result of his former status as Chairman and Chief Executive Officer of the Company. (Pfizer, *Proxy Statement*, March 13, 2009, at p. 10).

129. Defendant Kindler's principal professional occupation is his employment with Pfizer as its President, CEO and Chairman, pursuant to which he has received and continues to receive substantial monetary compensation and other valuable benefits, including more than $33 million in compensation during the Relevant Period. Defendant Steere, Pfizer's former CEO and Chairman, received substantial monetary compensation and other valuable benefits from Pfizer over the course of decades of employment, and currently, pursuant to his position as Chairman Emeritus, receives fees of at least $275,000 per year. Therefore, in accordance with the Board's own admission, a reasonable doubt is raised that Defendants Kindler and Steere lack independence, rendering them incapable of impartially considering a demand to commence and vigorously prosecute this action.

130. **Current Director Audit Committee Defendants Ausiello, Burns, Burt, Cornwell and Johnson**. At various times during the Relevant Period, current Board Directors Ausiello, Burns, Burt, Cornwell and Johnson served on Pfizer's Audit Committee. The specifics: Ausiello (2009), Burns (2005-2008), Burt (2001-2004, as Chair), Cornwell (2001-2008, with 2007-2008 as Chair), Johnson (since 2007).

131. Members of Pfizer's Audit Committee are charged, pursuant to Pfizer's Audit Committee Charter, with reviewing the Company's compliance with laws, regulations and internal procedures and controls, and with oversight of the same. Additionally, as per the Audit Committee Charter, the Audit Committee is further tasked with reviewing "policies with respect to risk assessment and risk management, and review [of] contingent liabilities and risks that may be material to the Company and major legislative and regulatory developments which could materially

impact the Company's contingent liabilities and risks".

132. Further, the additional oversight obligations taken on by the Company as a result of the Corporate Integrity Agreements – focusing specifically on misconduct of pharmaceutical marketing, promotion and sales, including exactly the misconduct detailed herein – devolved to substantial extent to the Audit Committee. Pursuant to the 2004 Corporate Integrity Agreement and the Audit Committee Charter, the Audit Committee received regular reports regarding Pfizer's compliance (or lack thereof) with relevant regulations. Prior to the 2004 Corporate Integrity Agreement , the Audit Committee met six or seven times per year; but after the 2004 Corporate Integrity Agreement , between 2005 and 2008, the Audit Committee doubled its meeting frequency, meeting between twelve and fourteen times each year.

133. Despite the foregoing responsibilities of Audit Committee Defendants Ausiello, Burns, Burt, Cornwell and Johnson, and the information and reporting provided to them, Defendants Ausiello, Burns, Burt, Cornwell and Johnson violated their fiduciary duties of due care, loyalty, and good faith in permitting the Company to continue to violate the laws and regulations as detailed herein despite being on notice of such violations. Accordingly, Defendants Ausiello, Burns, Burt, Cornwell and Johnson face a substantial likelihood of liability for their breach of fiduciary duties, and thus cannot appropriately consider demand. Any demand upon them is therefore futile, and excused.

134. **Current Director Corporate Governance Committee Defendants Ausiello, Brown, Gray and Horner**. At various times during the Relevant Period, current Board Directors Ausiello, Brown, Burns, Gray and Horner served on Pfizer's Corporate Governance Committee. The specifics: Ausiello (since 2007), Brown (since 2001), Gray (since 2001), and Horner (since 2001, as Chair between 2001-2003 and 2006-2008).

135. Members of Pfizer's Corporate Governance Committee are charged, pursuant to Pfizer's Corporate Governance Committee Charter, with reviewing matters of corporate governance and maintaining an informed status on Company issues relating to corporate social

responsibility, including monitoring "emerging issues potentially affecting the reputation of the... Company." During the Relevant Period, the Corporate Governance Committee met between four and ten times each year.

136. Pfizer's consistent, pervasive, illegal and dangerous marketing, promotion and sale of many of its best-selling drugs for off-label uses and/or at unapproved dosages – an issue that "emerged" consistently and directly to all Pfizer's Directors and to Corporate Governance Committee members – was not consistent with any sense of "social responsibility" and resulted in substantial impairment of the Company's reputation – particularly among regulators, who imposed upon Pfizer, because of its evident and wilful recidivism, the largest government criminal fine ever imposed on a public company for any legal violation.

137. Despite the foregoing responsibilities of Corporate Governance Committee members Defendants Ausiello, Brown, Gray and Horner that placed consideration of the misconduct detailed herein squarely before them, and despite the information and reporting provided to them, Defendants Ausiello, Brown, Gray and Horner violated their fiduciary duties of due care, loyalty, and good faith in permitting the Company to continue to violate the laws and regulations as detailed herein despite being on notice of such violations. Accordingly, Defendants Ausiello, Brown, Gray and Horner face a substantial likelihood of liability for their breach of fiduciary duties, and thus cannot appropriately consider demand. Any demand upon them is therefore futile, and excused.

C. Conclusion

138. In sum, as per subsection A *supra*, none of the current Director Defendants can properly consider demand, given their record of consistent conscious disregard (or affirmative approval) of Pfizer's widespread misconduct with respect to off-label marketing, promotion and sale of many of its most important pharmaceutical products. Moreover, as per subsection B *supra*, a majority of the current Directors (nine of the fourteen) are either admittedly lacking in independence (Kindler and Steere) or, as a result of serving on the Audit Committee and/or Corporate Governance Committee (Ausiello, Brown, Burns, Burt, Cornwell, Gray and Horner), which imposed heightened

and particular duties to identify and correct the misconduct at issue here, face a substantial likelihood of liability for their breaches of fiduciary duty. Demand as the above-named Defendants is therefore futile, and excused.

COUNT I
DERIVATIVE CLAIM FOR BREACH OF FIDUCIARY DUTY WITH RESPECT TO MANAGEMENT AND OVERSIGHT OF THE COMPANY'S BUSINESS
(Against All Defendants)

139. Plaintiff incorporates by reference and reallege seach and every allegation set forth above, as though fully set forth herein.

140. Defendants, by reasons of their positions as officers and directors of Pfizer, and because of their aibility to control the business and corporate affairs of Pfizer, owed and owe fiduciary duties to Pfizer and its shareholders. By reason of their fiduciary relationships, Defendants specifically owed and owe Pfizer the highest obligation of good faith and loyalty in the administration of Pfizer, including the oversight of Pfizer's compliance with federal laws and regulations governing the promotion, marketing and sale of pharmaceuticals. Further, Defendants had the fiduciary obligation to abide by (1) Pfizer's Corporate Integrity Agreements, and (2) Pfizer's Code of Conduct – both of which required Pfizer to comply with federal laws and regulations against improper promotion, marketing and sales of pharmaceuticals for off-label uses and dosages, and to comply with federal laws and regulations against improper provision of kickback payments to healthcare providers in order to induce further prescription of Pfizer products.

141. Defendants consciously violated their obligations, duties and responsibilities in, at least, the following ways:

(a) After receiving reports of Pfizer's improper and illegal promotion, marketing and sale of Bextra, Lyrica, Geodon and Zyvox for off-label uses and dosages, and after becoming aware of numerous additional "red flags" indicated widespread like practices, consciously disregarding such reports and activities and/or condoning them, but in any event deciding not to act

to stop and prevent them;

(b) After receiving further reports of Pfizer's illegal kickbacks to healthcare providers for prescribing various Pfizer products, consciously disregarding such reports and activities and/or condoning them, but in inay event deciding not to stop and prevent them with respect to at least nine Pfizer products– Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec – which included seven of Pfizer's nine best-selling and most important pharmaceuticals.

(c) Approving and/or consciously disregarding Pfizer's business strategy and culture of promoting, marketing and selling its pharmaceuticals for off-label uses and dosages and through improper and illegal kickback schemes to healthcare providers, in order to maximize short-term profits and growth at the expense of shareholders' long-term interests and Pfizer's reputation and goodwill.

142. Defendants wilfully ignored the obvious and pervasive compliance problems, brought repeatedly to their attention, with respect to Pfizer's marketing, promotion and sale of pharmaceuticals for off-label uses and dosages and via kickbacks to healthcare providers, all in contravention of federal laws and regulations, and failed to make a good faith effort to correct the problems or prevent their recurrence.

143. As a direct and proximate result of Defendants' conscious failure to perform their fiduciary obligations, Pfizer has sustained damages, not only monetarily, but also to its corporate image and goodwill. Such damage includes:

(a) The $1.2 billion criminal fine imposed upon Pfizer – the largest such fine in history – for the illegal off-label marketing of Bextra, together with a $105 million criminal forfeiture of Bextra proceeds, Pharmacia's guilty plea to felony violation of the FDCA, and Pfizer's agreement to a non-prosecution agreement subjecting it to severe restrictions and potential future sanctions;

(b) The further $1 billion civil fraud settlement with the DOJ (again, the largest such DOJ settlement in history), for Pfizer's illegal off-label promotion of Bextra, Lyrica, Geodon

and Zyvox, and for Pfizer's illegal kickbacks to healthcare providers to prescribe Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec;

(c) Damages and legal expenses Pfizer has had to pay to settle consumer protection actions brought by various States with respect to the illegal promotional, marketing and sales practices described herein, including the $33 million settlement Pfizer announced on September 2, 2009 with forty-two states and the District of Columbia regarding the illegal marketing of Geodeon;

(d) Damages and the costs of legal expenses to defend against numerous product liability suits by patients and consumers harmed by Pfizer's improper promotion, marketing and sale of its products for off-label uses and dosages, including a $745 million charge Pfizer announced on October 17, 2008 to settle product liability claims by plaintiffs who suffered injuries after falling victim to deceptive marketing of Bextra and Celebrex;

(e) Further damages and the costs of legal expenses to defenda against related, numerous consumer fraud actions alleging deceptive and illegal marketing of the above-mentioned Pfizer products, including a $89 million charge that Pfizer announced on October 17, 2008 to settle such suits with respect to Bextra and Celebrex;

(f) Damages and the costs of legal expenses to defend against eleven Qui Tam suits arising from current and former Pfizer employees reporting Pfizer's illegal conduct; and

(g) Loss of Pfizer's market value due to reputational and goodwill issues, following disclosure of Pfizer's misconduct and the ensuing record-breaking fines and settlements.

144. But for Defendants' abdication of their fiduciary duties, the Company would not have been damaged. As a result of the misconduct alleged herein, Defendants are liable to the Company.

COUNT II
DERIVATIVE CLAIMS FOR BREACH OF FIDUCIARY DUTY
(Against the Officer Defendants)

145. Plaintiff incorporates by reference and realleges each and every allegation set

forth above, as though fully set forth herein.

146. The Officer Defendants, by virtue of their positions as fiduciaries of the Company, owed duties of good faith, loyalty and truthful disclosure.

147. The Officer Defendants consciously violated and breached these duties by causing Pfizer to employ a business strategy of artificially increased pharmaceutical sales (and consequently revenues, income, and growth of the same) by engaging in illegal promotional, marketing and sales practices by numerous Pfizer employees with respect to numerous Pfizer pharmaceuticals for a prolonged period of time, in violation of FDA requirements and regulations, Federal healthcare program requirements and regulations, the Federal anti-kickback statute, and many of the Company's own public representations.

148. The Officer Defendants authorized and implemented Pfizer policies and practices encouraging widespread, illegal promotion, marketing and sale of Pfizer pharmaceuticals for off-label uses and dosages, as well as the provision of kickbacks to healthcare providers to induce further prescription of Pfizer products.

149. As a direct and proximate result of the Officer Defendants' breaches of fiduciary duty, the Company has sustained and will continue to sustain substantial harm, including the damages set forth at ¶ 143.

150. The Officer Defendants are liable to the Company as a result of the acts alleged herein.

COUNT III
DERIVATIVE CLAIM FOR UNJUST ENRICHMENT
(Against All Defendants)

151. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

152. By their wrongful acts and omissions, the Defendants and particularly the Officer Defendants were unjustly enriched at the expense of and to the detriment of Pfizer.

153. Plaintiff, as a shareholders and representative of Pfizer, seek restitution from

these Defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits and other compensation obtained by these Defendants, and each of them, from their wrongful conduct and fiduciary breaches.

COUNT IV
DERIVATIVE CLAIM FOR GROSS MISMANAGEMENT
(Against All Defendants)

154. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

155. Defendants had a duty to Pfizer and its shareholders to prudently supervise, manage and control Pfizers' operations and public disclosures.

156. Defendants, by their actions and by consciously disregarding or condoning the misconduct detailed herein, abandoned and abdicated their responsibilities and duties with regard to prudently managing the Company's business in a manner consistent with the duties imposed on them by law. By committing the misconduct alleged herein, Defendants breached their duties of due care, diligence and candor in the management and administration of Pfizer's affairs and in the use and preservation of Pfizer's assets.

157. During the course of the discharge of their duties, Defendants knew or recklessly disregarded the unreasonable risks and losses associated with their misconduct. Defendants caused Pfizer to engage in the scheme complained of herein, which they knew had an unreasonable risk of damage to Pfizer, thus breaching their duties to the Company. As a result, Defendants grossly mismanaged Pfizer.

COUNT V
DERIVATIVE CLAIM FOR WASTE OF CORPORATE ASSETS
(Against All Defendants)

158. Plaintiff incorporates by reference and realleges each and every allegation set forth above, as though fully set forth herein.

159. As a result of the misconduct described above, and by failing to properly consider the interests of the Company and its public shareholders, Defendants have caused Pfizer

to incur (and Pfizer may continue to incur) significant legal liability and/or legal costs to defend itself as a result of Defendants' unlawful actions.

160. As a result of this waste of corporate assets, Defendants are liable to the Company.

161. Plaintiff, on behalf of Pfizer, has no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, Plaintiff demands judgment as follows:

(a) Determining that this action is a proper derivative action maintainable under law, and that demand is excused;

(b) Against all Defendants and in favor of Pfizer the damages sustained by the Company as result of Defendants' breaches of fiduciary and contractual duties;

(c) Awarding to Pfizer restitution from Defendants, and each of them, and ordering disgorgement of all profits, benefits and other compensation obtained by Defendants during the Relevant Period;

(d) Directing Pfizer to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect the Company and its shareholders from a repeat of the damaging events described herein;.

(d) Awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and.

(d) Granting such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: October 6, 2009

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